

Amendments to the Claims:

This listing of claims replaces all prior versions and listings of claims in the application:

1. (currently amended) A method for monitoring the quality of a herbal medicine comprising the steps of

(a) providing a first sample of the herbal medicine, wherein the herbal medicine comprises phytochemicals selected from the group consisting of pyrrolidine, piperidine, pyrrolizidine, indolizidine, tropane, and nortropane alkaloids;

(b) extracting the sample with a polar solvent to produce (i) an extract of polar phytochemicals selected from the group consisting of pyrrolidine, piperidine, pyrrolizidine, indolizidine, tropane, and nortropane alkaloids, and (ii) a non-polar residue; and

(c) characterizing the extract of the polar phytochemicals.

2. (previously presented) The method of claim 1, wherein the polar extract is fractionated prior to characterization.

3. (previously presented) The method of claim 2, wherein the polar extract is fractionated by:

(a) ion-exchange chromatography to produce an extract enriched in ionic-compounds and a non-ionic residue; and then

(d) chromatographically fractionating the enriched extract of step (a) to yield one or more polar fractions comprising one or more ionic phytochemical(s).

4. (previously presented) The method of claim 3, wherein the chromatographic fractionation comprises gas-liquid chromatography (GC).

5. (previously presented) The method of claim 4, wherein the enriched extract is derivitized prior to gas-liquid chromatography.

6. (previously presented) The method of claim 3, further comprising the steps of: (i) scavenging the non-ionic residue for non-ionic species by subjecting the non-ionic residue to hydrophobic interaction or reversed-phase chromatography to produce a scavenged nonionic extract depleted in sugars; and (ii) characterizing the scavenged extract.

7. (previously presented) The method of claim 6, wherein the scavenged extract is fractionated prior to characterization.

8. (previously presented) The process of claim 7, wherein the scavenged extract is fractionated by chromatographic fractionation to yield one or more scavenged fractions comprising one or more non-ionic phytochemical(s).

9. (previously presented) The method of claim 8, wherein the chromatographic fractionation comprises high performance liquid chromatography (HPLC).

10. (withdrawn) The method of claim 1, further comprising: (i) extracting a second sample of the herbal medicine or sequentially extracting the non-polar residue of the first sample with a non-polar solvent to produce a non-polar extract; and (ii) characterizing the non-polar extract.

11. (withdrawn) The method of claim 10, wherein the non-polar extract is fractionated prior to characterization.

12. (withdrawn) The method of claim 11, wherein the non-polar extract is fractionated by: (i) subjecting the non-polar extract to hydrophobic interaction or reversed-phase chromatography to produce an extract depleted in fats and chlorophyll; and (ii) chromatographically fractionating the depleted extract to yield one or more non-polar fractions comprising one or more non-polar phytochemical(s).

13. (withdrawn) The method of claim 12, wherein the chromatographic fractionation comprises high performance liquid chromatography (HPLC) and/or gas-liquid chromatography (GC).

14. (withdrawn) The method of claim 1, wherein the polar and/or non-polar extracts are characterized:

- (a) functionally; and/or
- (b) physically, and/or
- (c) chemically.

15. (withdrawn) The method of claim 14, wherein the functional characterization comprises a biological assay.

16. (withdrawn) The method of claim 14, wherein the physical characterization is selected from the group consisting of:

- (a) quantification of the phytochemical component(s);
- (b) measurement of the purity of the constituents;
- (c) determination of molecular weight (or molecular weight distribution or various statistical functions thereof in the case of fractions which comprise a plurality of different phytochemical constituents);
- (d) determination of the molecular formula(e) and
- (e) spectral analysis.

17. (withdrawn) The method of claim 16, wherein the spectral analysis produces:

- (e) mass spectra, and/or
- (f) chromatographic data, and/or
- (g) photodiode array (PDA) spectra, and/or
- (h) nuclear magnetic resonance (NMR) spectra.

18. (withdrawn) The method of claim 16, wherein spectral analysis is coupled with fractionation of the extract.

19. (withdrawn) The method of claim 14, wherein the chemical characterization measures:

- (a) the chemical reactivity of phytochemical constituent(s); and/or
- (b) the solubility of phytochemical constituent(s); and/or
- (c) the stability and melting point of phytochemical constituent(s).

20. (previously presented) The method of claim 2, wherein the fractionation of the extract yields a defined fraction or an isolated phytochemical.

21. (withdrawn) The method of claim 1, wherein the characterization yields a phytochemical profile.

22. (withdrawn) The method of claim 21, further comprising the step of analyzing the phytochemical profile to determine whether one or more bioactive principle(s) are present in the sample(s).

23. (withdrawn) The method of claim 21, further comprising the step of analyzing the phytochemical profile to determine whether one or more bioactive marker(s) are present in the sample(s).

24. (withdrawn) The method of claim 21, further comprising the step of analyzing the phytochemical profile to determine whether it meets a standard specification.

25. (withdrawn) A method for identifying a bioactive principle in a herbal medicament, the method comprising the steps as defined in claim 1.

26. (withdrawn) The method of claim 25, wherein the sample is a blood sample which is obtained by administering a sample of the herbal medicine to a subject and then extracting a blood sample from the subject.

27. (withdrawn) A process for producing a herbal medicine comprising the step of monitoring the quality of the herbal medicine by a method as defined in claim 1.

28. (withdrawn) A herbal medicine obtainable by the process of claim 27.

29. (withdrawn) The method of claim 15, wherein the biological assay is selected from the group consisting of:

- (a) *in vivo* or *in vitro* assays,
- (b) enzyme inhibition assays,
- (c) receptor binding assays,
- (d) cellular assays,
- (e) immunoassays,
- (f) anti-microbial activity assays, and
- (g) toxicity assays.

30. (withdrawn) The method of claim 29, wherein the enzyme inhibition assay involves glycosidase and/or lipase inhibition.

31. (withdrawn) The method of claim 29, wherein the cellular assays are selected from the group consisting of cell replication assays, cell-pathogen assays, cell-cell interaction assays, and cell secretion assays.

32. (withdrawn) The method of claim 29, wherein the anti-microbial activity are bacterial and viral cell-binding and/or replication assay.

33. (withdrawn) The method of claim 29, wherein the toxicity assays are LD₅₀ assays.

34. (withdrawn) The method of claim 16, wherein the determination of the molecular formula(e) is accomplished by nuclear magnetic resonance (NMR).

35. (withdrawn) The method of claim 17, wherein the chromatographic data includes spectra, column retention times, and/or elution profiles.

36. (withdrawn) The method of claim 17, wherein the PDA spectra are obtained in both UV and visible ranges.

37. (withdrawn) The method of claim 17, wherein the NMR spectra are spectral data sets obtained via ¹H and/or ¹³C NMR.

38. (withdrawn) The method of claim 18, wherein GC-MS and/or HPLC-PDA-MS are used.